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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,552	11/28/2000	Dale B. Schenk	15270J-004761US	7133

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EXAMINER	
NICHOLS, CHRISTOPHER J	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/724,552	Applicant(s) SCHENK ET AL.	
	Examiner Christopher Nichols, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) *1-46 and 48-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47 and 66-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11,15.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with **traverse** of Group III (claims 47 and 67-68) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the species are not mutually exclusive as in MPEP 806.04(f) and thus should not be restricted. This is persuasive. The species requirement as set forth in Paper No. 8 (2 July 2002) is hereby withdrawn. Claims 1-46 and 48-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10. The restriction requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, and/or Claims

2. The Preliminary Amendment filed 25 March 2003 (Paper No. 11) has been entered in full. Claim 47 has been amended and claims 69-71 have been added. Claims 47 and 67-71 are under examination.

Sequence Requirements

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below. This application discloses an amino acid sequence on Figures 19 and 20 without the appropriate SEQ ID NO. Correction is required.

Drawings

4. The drawings are objected to because Figure 10 contains two panels which must be labeled "10A" and "10B" in both the drawings and the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawing of Figure 11 is objected to because the figure lacks an appropriate legend which indicates the peptide treatment groups as indicated and described in the figure and specification, see in particular pp. 62-63 and brief description of the drawings, p. 7. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Applicants may alternatively choose to amend the brief description of the drawings so that it clearly reflects the groups represented in the Figure. Such amendment would be considered an appropriate correction so as to obviate abandonment of the application.

Information Disclosure Statement

6. The information disclosure statements filed 19 February 2003 (Paper No. 19) contains particular references (**#144, #161, #162, #186, #220, #222, #223, #224, #304**) which fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because they lack a relevant public availability date. Those references have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised

that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims **67** and **68** are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 108 and 109 of copending Application No. 09/979701 and claims 67 and 68 of copending Application No. 09/724273. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Non-Statutory Double Patenting Rejection

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise

extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims **47** and **67-71** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-57, 62, 84-131,** and **137** of Application No. 10/010942. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are either anticipated by, or would have been obvious over the '942 claims. Both instant claims and the '942 claim are drawn to a pharmaceutical composition of an anti-Aβ antibody that specifically binds to an epitope within residues 1-7 of Aβ. Instant claims recite administration of antibodies comprising antibodies immunospecific for an epitope within residues 1-7 of Aβ which is within the scope of residues 1-5 and 3-6 of Aβ in '942 (the claims are drawn to an immunoglobulins which has the immunospecificity of 3D6 or 10D5 whose epitopes are defined as residues 1-5 and 3-6 of Aβ, respectively, in the instant specification at Table 16 on page 97). Thus, it would have been *prima facie* obvious to the skilled artisan that the claims in both instant, the '942 application would fully encompass a pharmaceutical composition comprising an anti-Aβ antibody with the same immunospecificity. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims **47** and **67-71** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **47** and **67-71** of

Application No. 09/724552 and claim **47** of Application No. 09/724551. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are either anticipated by, or would have been obvious over the '552 and '551 claims. Both instant claims, the '552 claims, and the '551 claim are drawn to a pharmaceutical composition of an anti-Aβ antibody that specifically binds to an epitope within residues 1-10 of Aβ. Instant claims recite administration of antibodies comprising antibodies immunospecific for an epitope within residues 1-10 of Aβ which is identical to the scope of residues 1-10 of Aβ in '552 and '551. Thus, it would have been *prima facie* obvious to the skilled artisan that the claims in both instant, the '552 application, and the '551 application would fully encompass a pharmaceutical composition comprising an anti-Aβ antibody with the same immunospecificity. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims **47, 67,** and **69-71** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim **88** of copending Application No. 09/979701, claim **47** of copending Application No. 09/724273. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are either anticipated by, or would have been obvious over the '701 or '273 claims. Both instant claims and the '701 and '273 claims are drawn to a pharmaceutical composition comprising an anti-Aβ antibody that binds to an epitope within residues 1-10 of Aβ. The instant claims recite administration of antibodies comprising antibodies immunospecific for an epitope within residues 1-4, 1-5, 1-6, and 1-10 of Aβ as does the '701, and '273 recites an epitope within residues 1-10 of Aβ. Thus, it would have been prima facie obvious to the skilled artisan that the claims in both instant and the '701 or '273 application would fully encompass a pharmaceutical composition comprising an anti-Aβ antibody with the same immunospecificity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim **47** is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the epitope to which the antibody binds to on the Aβ protein. In light of the specification and other claims, the Examiner interprets this as an unintentional omission by the Applicant which may be remedied by adding the limitation "an epitope" in line 2 of claim 47.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims **47**, **67**, and **68** are rejected under 35 U.S.C. 102(a) as being anticipated by Akiyama *et al.* (15 February 1999) "Occurance of the Diffuse Amyloid β-Protein (Ab) Deposits with Numerous Aβ-Containing Glial Cells in the Cerebral Cortex of Patients with Alzheimer's

Disease." GLIA **25**(4): 324-331. Akiyama *et al.* teaches a monoclonal antibody 6E10 with an epitope of residues 1-17 of Aβ. While the epitope listed by Akiyama *et al.* is the epitopes claimed in the instant application, the instant specification discloses that monoclonal antibody 6E10 has an epitope of residues 5-10 of Aβ (pp. 97, Table 16). Since the antibodies have the same name and are specific for the same protein, the two 6E10 antibodies are taken by the Examiner to be identical thus meeting the limitations of claims 47 and 67. Further, Akiyama *et al.* teaches the the antibody 6E10 does not stain β-amyloid deposits in post-mortem tissue of Alzheimer's pateints (pp. 328). This does, however, meet the limitations of claim 68.

13. Claims **47**, **67, 68,** and **69** are rejected under 35 U.S.C. 102(b) as being anticipated by Walker *et al.* (July 1994) "Labeling of Cerebral Amyloid *In Vivo* with a Monoclonal Antibody." Journal of Neuropathology and Experimental Neurology **53**(4): 377-383.

14. Walker *et al.* discloses the monoclonal antibody 10D5 which is specific to an epitope of residues 1-16 of Aβ (pp. 377). While the epitope listed by Walker *et al.* is not within the epitopes claimed in the instant application, the instant specification discloses that monoclonal antibody 10D5 has an epitope of residues 3-6 of Aβ (pp. 97, Table 16). Since Walker *et al.* and the instant application share a common inventor (Dr. Dale B. Schenk), the two 10D5 antibodies are taken by the Examiner to be identical. Further, Walker *et al.* teaches a method of using the 10D5 in a saline solution (a pharmaceutical composition) to label amyloid deposits in aged monkeys (Figures 1-5). Thus Walker *et al.* meets the limitations of claims 47, 67, 68, and 69.

15. Claims **47** and **67** are rejected under 35 U.S.C. 102(b) as being anticipated by Johnstone *et al.* (27 March 1996) "Nuclear and Cytoplasmic Localization of the b-Amyloid Peptide (1-43)

in Transfected 293 Cells." Biochemical and Biophysical Research Communications **220**(3): 710-718.

16. Johnstone *et al.* discloses the monoclonal antibody 10D5 (pp. 710). While Johnstone et al. do not list the epitope, the instant specification discloses that monoclonal antibody 10D5 has an epitope of residues 3-6 of Aβ (pp. 97, Table 16). In addition, Johnstone *et al.* credits Dr. Dale B. Schenk with giving Johnstone *et al.* the 10D5 antibody (Materials and Methods, pp. 711). Therefore two 10D5 antibodies are taken by the Examiner to be identical. Thus Johnstone *et al.* meets the limitations of claims 47 and 67.

17. Claims **47** and **67** are rejected under 35 U.S.C. 102(b) as anticipated by Szendrei *et al.* (April 1996) "The effects of aspartic acid-bound isomerization on in vitro properties of the amyloid β-peptide as modeled with N-terminal decapeptide fragments." International Journal of Peptide & Protein Research **47**(4): 289-296.

18. Szendrei *et al.* discloses the monoclonal antibody 6E10 (pp. 289). While the epitope is not listed by Szendrei *et al.*, the instant specification discloses that monoclonal antibody 6E10 has an epitope of residues 5-10 of Aβ (pp. 97, Table 16). Since the antibodies are both monoclonal and specific for Aβ, the two 6E10 antibodies are taken by the Examiner to be identical.

19. Claims **47** and **67** are rejected under 35 U.S.C. 102(b) as being anticipated by US 5593846 (14 January 1997) Schenk *et al.*

20. US 5593846 discloses the monoclonal antibody 10D5 which is specific to an epitope of residues 1-16 of Aβ (Col. 13 lines 48-60). While the epitope listed by US 5593846 is not within the epitopes claimed in the instant application, the instant specification discloses that monoclonal

antibody 10D5 has an epitope of residues 3-6 of Aβ (pp. 97, Table 16). Since US 5593846 and the instant application share a common inventor (Dr. Dale B. Schenk), the two 10D5 antibodies are taken by the Examiner to be identical. Further, US 5593846 teaches a method of using the 10D5 in a buffer solution (a pharmaceutical composition) (Col. 14 lines 45-60). Thus US 5593846 meets the limitations of claims 47 and 67.

Summary

21. No claims are allowed.

22. The following articles were found by the Examiner during the art search for the instant application and are here made of note:

a. US 2002/0009445 A1 (24 January 2002) Du *et al.*

b. US 5721130 (24 February 1998) Seubert *et al.*

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elizabeth C. Kemmerer

CJN
May 16, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER